

### Remarks/Arguments

This amendment is in response to the Office Action dated April 14, 2009.

Claims 1, 2, 4, 5, 11, 14 and 15-24 remain in this application. The amendments to claims 1, 11 and 21 find support at Page 6, lines 6-11 and claim 20 and the amendment to claim 22 finds support in existing claim 20. New claims 25 and 26 have been added and find support in the Specification at Page 4, line 18 to Page 5, line 18.

Claims 1, 2, 16-19 have been rejected under 35 USC 102(b) by Mackal (US 2859932).

Applicants disagree. As the standard for anticipation is one of strict identity and "the reference must teach every aspect of the claimed invention either explicitly or inherently" (MPEP section 706.02IV, lines 6 and 7) and the cited reference has failed to teach several of the claimed elements, this reference is not and cannot be an anticipatory reference. As such, the rejection based on 35 USC 102(b) is respectfully requested to be withdrawn as it fails to provide a reference which contains all of the claimed elements of the present claims and therefore no basis for rejection under 35 USC 102 has been properly made.

Mackal discloses that rigid (metal) stems had been used with such flexible devices before and were not acceptable as they can be permanently deformed, are prone to puncture the wall of the device, scratch adjacent surfaces, and deform and weaken the plastic device during long term storage. The solution according to Mackal is to use a flexible elastomeric valve (PVC is preferred) (column 2, line 58 "are made of elastic plastic material".... and Column 5, lines 11-12 "molded from polyvinyl chloride which is relatively soft and elastic".....) on its flexible rubber inflatable device or toy. Moreover the plastic it discloses is not taught or suggested to be steam sterilizable.

The examiner states that any can form a steamable surface because any surface is steamable.

Applicants disagree in that while any material may be steamed most will suffer irreversible damage or destruction rendering that device or its steamed face useless. One of ordinary skill in the art would not select a material that would not withstand steam sterilization and use it in a location knowing that it is required to survive steam exposure.

Moreover, at Column 5, lines 55-57 it admits it is not a sterile system as it can be pulled apart to remove **foreign matter** that has entered the valve.

Moreover, the plunger 15 of the reference has an outer dimension, at several if not all locations, that is equal to or greater than that of the bore in which it resides so that it creates a slidable friction fit between the plunger and the bore wall, (Column 5, lines 20-39) or the hollow stem of the plunger and the wall of the opening 13 (Column 4, lines 19-25), etc . The present claims require the plunger has a diameter less than that of the bore.

The office action alleges the existence of a cam and cam slot formed in the body as is required by the claims, yet Applicants fail to find such a system in the reference even with the annotation provided by the Examiner. At best the reference teaches the use of a shoulder 26 that can in one position abut against a rib 37 to limit its travel to some degree. The shoulder rides along the inner surface of the 17 of the valve body. Even giving this interpretation wide latitude, it fails to teach the present invention as **there is no cam slot in the body** as is required by the claims.

The claims require the use of a handle and no such handle is taught by the reference. Element 22 is described by the reference as a "hollow stem 22 which has sealing but sliding contact with the wall of the

opening 13..." (Column 4, lines 19-25). Applicants contend no handle as that term is commonly used and know is taught by the reference.

Lastly, the claims require the use of seals between the plunger and the body bore to form a liquid tight seal. Mackal does not do so. It relies instead upon a friction fit between its components to form the seal (Column 5, lines 20-39) and (Column 4, lines 19-25).

Claims 4, 5 and 11 have been rejected under 35 USC 103(a) over Mackal in view of Tessman et al (US 6210372). Applicants disagree.

The office action argues it would have been obvious to form the device of Mackal using a thermoplastic such as polyetherimide so the device could withstand sterilization.

Mackal uses a soft elastic material. This is done so that the two elements can be molded separately and then assembled together by "temporarily deforming them, the parts then resuming their normal relaxed shape...." (Column 2, 44-45) and see (Column 5, lines 40-58). Moreover, it relies on the soft elastic material of the body and plunger to let its two elements have a slidable friction fit between each other in order to form a seal. Lastly, it teaches that rigid materials are not acceptable in its application as they can be permanently deformed, are prone to puncture the wall of the device, scratch adjacent surfaces, and deform and weaken the plastic device during long term storage. The solution according to Mackal is to use a flexible elastomeric valve (PVC is preferred) (column 2, line 58 "are made of elastic plastic material".... and Column 5, lines 11-12 "molded from polyvinyl chloride which is relatively soft and elastic".....) on its flexible rubber inflatable device or toy.

Given the clear and unambiguous teachings of Mackal as to nature of the material that must be used in the manufacture of its device so that it can be assembled and so it can create the frictional sliding seal between them, one of ordinary skill in the art would not have thought to substitute a hard, rigid plastic such as

polyetherimide for both the plunger and body of Mackal as one would not be able to make or assemble the product as taught by Mackal nor achieve the slidable friction seal between the elements that Mackal requires.

As such the reference fails to suggest the present invention and the prima facie case of obviousness has not been established or if established has been successfully rebutted above.

Claims 14, 21-24 have been rejected under 35 USC 103(a) by Mackal (US 2,859,932) in view of Leason et al (US 5360413).

Applicants disagree.

It is argued in the office action that Leason teaches a sanitary flange 25 and it would have been obvious to use that flange on Mackal to attach it to a component without contamination. Yet Leason does not teach a flange being capable of attaching to an upstream element. Instead it has a flange that is exposed (which leads to contamination and is at best aseptic but never sterile) and a displaceable portion in that flange that when contacted with a syringe or similar device pushes in that portion exposing it to the interior of the syringe. Moreover Leason uses an alcohol wipe to aseptically clean its exposed surface and fails to teach or suggest using a steam exposure.

Mackal is designed and taught as being sealed about its middle portion to a surface of the device to which it is attached. Mackal uses a flange 16 at that point that is heat bonded to the material of the device to which it is attached (a blow up toy for example). Moreover as mentioned above Mackal does not care about contamination as it teaches to simply take the valve apart and clean out the foreign matter from it and then reassemble it.

There is no teaching, suggestion or motivation to use an exposed unconnected flange of Leason in the device of Mackal. Moreover Mackal isn't worried about contamination and faces that issue by simply

taking the device apart and cleaning it. There is no motivation in Mackal to use the flange of Leason as alleged in the office action. As such the prima facie case of obviousness has been successfully rebutted.

Additionally neither Leason nor Mackal teach the use of seals formed on one component to liquid tightly seal the other component to it. Instead they both rely upon a friction fit between the components to form a seal. The present invention as claimed in claims 21 and 22 would not have been obvious from this cited combination.

Lastly neither Leason nor Mackal teach the use of a tube connected to a port or the tube being connected to a collection bag as is required by claim 22. The present invention as claimed in claim 22 would not have been obvious from this cited combination.

Claim 15 has not been rejected and is therefore assumed to be in condition for allowance.

Likewise claim 20 has been rejected and is assumed to be in condition for allowance.

New claims 25 and 26 are also neither taught nor rendered obvious from the cited prior art for the same reasons stated above in relation to the other existing claims and are believed to be in condition for allowance.

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Reconsideration and allowance of the claims is respectfully requested in view of the foregoing amendments and remarks.

Respectfully submitted,

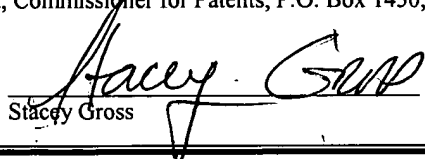
  
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